

REMARKS**RECEIVE**

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Reconsideration of the above-captioned application in light of the foregoing amendment and the following remarks is respectfully requested.

Claims 1-7 and 10 remain in the application. Only Claim 1 is in independent form. Claims 8 and 9 have been cancelled. Claims 11-20 have been withdrawn from consideration, by the Examiner, as being directed to a non-elected invention. A marked copy of Claim 1 is enclosed showing the changes made by the above amendments.

Claims 1, 2, and 7-10 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by WO 93/11749 ('749). The '749 reference teaches a solid pharmaceutical dispersion combining a poorly water-soluble drug with a polymer carrier such as polyvinylpyrrolidone (PVP) and a transition compound which partially solubilizes the drug and/or plasticizes the polymer. As set forth in the amended claims, Claim 1 defines a sparingly water-soluble pharmaceutical crystalline particulate at least partially coated with a solidified matrix consisting of a water-soluble polymer. Since the '749 reference requires a transition compound which at least partially solubilizes the drug in addition to the polymer carrier, the '749 reference does not teach a pharmaceutical dosage form defined by amended Claim 1. Since the '749 reference does not show this feature, the claims are clearly patentable over the '749 reference, and reconsideration of the amended claim is respectfully requested.

Claims 1-10 stand rejected unpatentable over 35 U.S.C. §103(a) as allegedly being unpatentable over Olefsky et al. in view of Grabowski et al. Reconsideration of the rejection under 35 U.S.C. §103(a) as unpatentable over Olefsky et al. in view of Grabowski et al., as applied to the amended claims, is respectfully requested.

The Olefsky et al. reference was held to teach troglitazone and rosiglitazone in solid form preparations. The Grabowski et al. reference was held to teach delayed release compositions which are solid compositions comprising an active ingredient and a polymer.

As set forth above, Claim 1 defines the solidified matrix as consisting of a water-soluble polymer. While Grabowski et al. disclose the use of two polymers which can be the same polymers having different viscosities, review of the Table detailing examples 1-7 teaches that when both polymer A and polymer B are hydroxymethylcellulose, an auxiliary agent C was incorporated in each example thereof. The auxiliary agent C utilized in the examples when both polymer A and polymer B were hydroxypropylmethyl-cellulose was polyethylene glycol stearate. As defined in Claim 1, the pharmaceutical agent is in crystalline form. Further, the solidified matrix of Claim 1 is defined as consisting of a water-soluble polymer. By definition, Claim 1 would exclude the solubilizing agent/transition compound (polyethylene glycol) as required in the Grabowski et al. reference as this would produce a non-crystalline pharmaceutical agent through solubilization.

Accordingly, in view of the foregoing, Applicant respectfully submits that neither the Olefsky et al. nor the Grabowski et al. references alone or in combination render obvious the presently claimed invention. Even assuming, arguendo, and in contradiction to the prevailing law, that the Olefsky et al. reference and the Grabowski et al. reference were combined, the resulting combination would yield a partially solubilized pharmaceutical agent coated with a water-soluble polymer and a transition compound/solubilizing agent. The invention as defined by amended Claim 1 is clearly patentable over the resultant combination and reconsideration of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, Applicant submits that the application is in condition for allowance, which allowance is respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account 23-0455.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "D R Kurlandsky", written over a horizontal line.

David R. Kurlandsky

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Attachment - Version with Markings to Show Changes Made

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Twice amended) A solid particulate pharmaceutical dosage form suitable for oral delivery comprising a sparingly water-soluble pharmaceutical agent in crystalline particulate form, wherein said particulate is at least partially coated with a solidified matrix [comprising] consisting of a water-soluble polymer having a melting temperature less than that of the pharmaceutical agent.